MAR 8 2002

Amendments to Denka Seiken Co., Ltd.
Pre-market Notification
Lp(a)-Latex SEIKEN Assay Kit

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I. 510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510 (k) number is: K013359

(A)(1) Submitter's name: Denka Seiken Co., Ltd.

Submitter's address: 3-4-2, Nihonbashi kayabacho
Chuo-ku
Tokyo, Japan 103-0025

Submitter's telephone number: (03) 3669-9421

Contact Person: Mr. Yousuke Meguro
Assistant Manager
International Sales and Business Development Dept.

Date Summary Prepared: February 1, 2002

(2) Trade or proprietary device name: Lp(a)-Latex SEIKEN Assay
(3) Common or usual name: Lipoprotein (a) assay
Classification Name: Low density Lipoprotein Immunological test system
Panel: Immunology
Class: II

(3) Legally marketed predicate device(s): SPQ Test System Antibody Reagent Set for Lp(a) [DiaSorin Inc.](K982708)

(4) Subject device description:

The Lp(a)-Latex SEIKEN Assay Kit is a latex *in vitro* diagnostic immunoassay for the quantitative determination of Lipoprotein (a) in human serum and plasma. Antigen in the sample binds to the specific anti-Lp(a) antibody, which has been adsorbed to latex particles, and agglutinates. The agglutination is detected as an absorbance change when read on Hitachi 917 analyzer, with the magnitude of the change being proportional to the quantity of Lp(a) in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentrations.

(5) Subject device intended use:

The Lp(a)-Latex SEIKEN Assay kit is an *in vitro* diagnostic test for the quantitative determination of lipoprotein (a) [Lp(a)] in human serum and plasma samples with Hitachi 917 analyzer. The measurement of Lp(a) is useful in evaluating lipid metabolism disorders and assessing atherosclerotic cardiovascular disease in specific populations, when used in conjunction with clinical evaluation and other lipoprotein tests.

(6) Performance data:

The Lp(a)-Latex SEIKEN Assay and the predicate device, SPQ Test System Antibody Reagent Set for Lp(a) methods and reagents have only minor difference that do not affect the performance, safety or effectiveness of the measurement.

Comparative performance studies, when conducted on 105 donor samples, yielded a correlation coefficient upon comparison of the Lp(a)-Latex SEIKEN and the SPQ Test System Antibody Reagent Set for Lp(a) of $r = 0.919$.

Precision studies were performed using medium and high control materials. % CV for the medium control was 2.00%; for the high control, the % CV was 1.26.

The lower level of detection (sensitivity of the assay) is at 2.0 mg/dL, with the assay range up to 80.0 mg/dL.

These findings demonstrate that the performance of the Lp(a)-Latex SEIKEN Assay kit is both robust and substantially equivalent to the predicate device, SPQ Test System Antibody Reagent Set for Lp(a).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Yousuke Meguro
Assistant Manager
International Sales and Business Development Department
Denka Seiken Co., Ltd.
3-4-2, NIHONBASHI-KAYABACHO
CHUO-KU, TOKYO
JAPAN 103-0025

MAR 8 2002

Re: k013359
Trade/Device Name: Lp(a)-Latex SEIKEN Assay Kit
Regulation Number: 21 CFR 866.5600
Regulation Name: Low density lipoprotein immunological test system
Regulatory Class: Class II
Product Code: DFC
Dated: February 1, 2002
Received: February 4, 2002

Dear Mr. Meguro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

C. Indications for use of the Device

510(k) Number): K013359

Device Name: Lp(a)-Latex SEIKEN Assay Kit

Indications for Use:

The Lp(a)-Latex SEIKEN Assay kit is an *in vitro* diagnostic test for the quantitative determination of lipoprotein (a) [Lp(a)] in human serum and plasma samples with Hitachi 917 analyzer. The measurement of Lp(a) is useful in evaluating lipid metabolism disorders and assessing atherosclerotic cardiovascular disease in specific populations, when used in conjunction with clinical evaluation and other lipoprotein tests.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013359

Prescription Use X or Over-the-Counter Use _____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)